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13
14 **UNITED STATES DISTRICT COURT**
DISTRICT OF NEVADA

15
16 REBECCA GRAHAM and CHARLES
GRAHAM, on Behalf of Justin Graham,
17 (formerly) a Minor; and JUSTIN GRAHAM,

18 Plaintiffs,

19 v.

20 I-FLOW CORPORATION,

21 Defendants.

Case No.: 2:09-CV-00531-KJD-(RJJ)

PLAINTIFFS' SECOND AMENDED
COMPLAINT

PLAINTIFFS' SECOND AMENDED COMPLAINT

Plaintiffs, Justin Graham, and his parents, Rebecca Graham and Charles Graham, individually and as legal guardians and natural parents of Justin Graham, by and through their undersigned attorneys, hereby allege and aver in support of their Second Amended Complaint as follows:

PREAMBLE

1. Pain pumps are medical devices that are used to manage post-operative pain. Orthopedic surgeons use pain pumps after surgery to deliver, by way of a catheter, continuous doses of pain relief anesthetic for several days directly into the shoulder.

2. The pumps first used in the 1990s had limited amounts of anesthetics and a limited flow rate. Beginning in the late 1990s, however, the manufacturers increased the anesthetic capacity of the pumps (high volume), and with the knowledge and encouragement of the pain pump manufacturers, surgeons began to insert the catheter directly into the shoulder joint space.

3. Continuous injection of these anesthetics directly into the shoulder joint can cause serious and permanent damage to the shoulder joint cartilage. The damage occurs when the anesthetic kills the chondrocytes (cartilage cells) and causes cartilage to degenerate progressively. Patients injured by pain pumps develop a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible, disabling, and extremely painful condition. These patients typically require additional surgeries, including complete shoulder joint replacement. As written in the medical literature, "the prognosis for these shoulders is grim."¹

4. The pain pump companies manufactured and marketed these devices without doing a single study to determine the safety of high-volume pain pumps, or what damage could be caused

¹ Petty, D.H. *et al.*, *Glenohumeral Chondrolysis After Shoulder Arthroscopy*, Am. J. Sports Med. 32:(2)509 (2004).

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1 when physicians placed the catheter into the shoulder, much less directly into the shoulder joint
2 space. Instead, they encouraged orthopedic surgeons to use the pumps and anesthetics, in tandem,
3 in an untested and dangerous manner.

4 5. Indeed, the pain pump manufacturers sought approval from the Food and Drug
5 Administration (“FDA”) for the placement of the catheter in the shoulder joint space beginning in
6 the late 1990’s. For lack of safety information, the FDA *rejected* their applications for orthopedic
7 and intra-articular placement multiple times. Yet, the pump manufacturers chose not to advise
8 physicians about these dangers, not to advise patients of these risks, not to tell physicians that their
9 FDA applications were rejected, and continued to sell and market these pumps with reckless
10 indifference – all to the detriment of thousands of patients generally, and the Plaintiffs herein, in
11 particular.

12 6. On November 13, 2009, the FDA issued a directive in which it noted that pain pumps
13 and the anesthetics used in them were defective for their failure to warn regarding the risk of
14 shoulder chondrolysis and directed pain pump and anesthetic manufacturers to include such
15 warnings. The FDA further noted that the information on dose administration was insufficient in so
16 far as there was no information about maximum daily dose or intra-articular use with pain pumps.
17 Although this FDA directive was based upon reported adverse events

18 7. Had I-Flow conducted those studies that the FDA required back in the 1990s, as they
19 were obligated to do, they would easily have determined that exposure to pain pump anesthetics
20 over time in the shoulder is exceedingly dangerous and contraindicated. Had they performed the
21 appropriate tests timely, Justin’s physicians would not have used a pain pump, and he would not
22 have suffered the devastating effects of shoulder chondrolysis. With reckless indifference to the
23 health and safety of these patients, I-Flow chose to place profits over safety by choosing not to do
24 those studies necessary to determine the dangers of their products.

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I. JURISDICTION / VENUE

8. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states.

9. Venue is proper in this jurisdiction pursuant to 28 U.S.C § 1391(a)(2) because Defendant regularly solicits and engages in business and other persistent courses of conduct, and derives substantial revenues from goods used in the State of Nevada. Defendant is a corporation maintaining sufficient minimum contacts with this judicial district to subject the corporation to personal jurisdiction here. While still a minor child, Justin Graham was injured as a result of the Defendant's products in Clark County, Nevada.

10. The amount in controversy in this matter exceeds \$75,000.00, exclusive of interest and costs.

II. PARTIES

11. Plaintiffs, Justin Graham (hereinafter sometimes referred to as "Justin" or "Plaintiff") and his parents, Rebecca Graham and Charles Graham, are citizens and residents of Clark County, Nevada. Rebecca and Charles Graham are the biological parents and natural guardians of their son, Justin Graham, who was a minor at the time of the alleged injury, but is now an adult. As such, Plaintiffs, Rebecca and Charles Graham were, at all times relevant hereto, required to care for the needs and necessities of their minor child, Justin Graham, which included his medical care.

12. Defendant I-Flow Corporation ("Manufacturing Defendant") designs and manufactures products called "pain pumps," continuous infusion anesthetic medical devices intended to deliver, via catheter, continuous doses of pain relief medication directly into the shoulder. The pain pumps deliver anesthetic pain medication directly into the operative site for 48 hours or more immediately following shoulder surgery. This Defendant held itself out to the medical and lay communities generally, and to Justin Graham, his Plaintiff parents, and his

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1 physician in particular, as a manufacturer, provider and seller of medical devices, including pain
2 pumps. Defendant I-Flow Corporation (“I-Flow”) is a Delaware corporation with its principal place
3 of business at 20202 Windrow Drive, Lake Forest, California 92630. At all times relevant hereto, I-
4 Flow was engaged in Nevada in the testing, manufacturing, labeling, marketing, distributing,
5 promoting, and selling of pain pumps.

6 **III. FACTUAL BACKGROUND**

7 13. Justin Graham was a 16-year-old high school student living with his parents in Las
8 Vegas when he and his parents consulted with his orthopedic surgeon, Jason Nielson, M.D., about a
9 problem he was experiencing with his shoulder. Dr. Nielson recommended surgery to repair
10 Justin’s right shoulder labral tear. On or about August 13, 2007, Justin underwent routine
11 arthroscopic surgery.

12 14. During his surgery, Dr. Nielson affixed to Justin’s shoulder a "pain pump,"
13 specifically an ON-Q® PainBuster® Post-Op Pain Relief System (ON-Q® PainBuster®), with
14 continuously injected anesthetic, Marcaine® .5% “plain,” i.e. without epinephrine.

15 15. Justin’s pain pump, through a catheter emanating from the pump and implanted
16 under the skin and into his shoulder joint, injected the anesthetic on a continuous basis following his
17 surgery. The ON-Q® PainBuster® pain pump was manufactured by the Defendant, I-Flow.

18 16. The continuous injection of anesthetic drugs over time directly into Justin’s shoulder
19 joint after his August 13, 2007 surgery caused him serious and permanent cartilage damage. As a
20 result, Justin suffered a narrowing of the joint space and/or a condition called "glenohumeral
21 chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint, an
22 irreversible, disabling, and extremely painful condition.

23 17. Justin has already undergone additional surgeries as a result of the narrowing of the
24 joint space and/or chondrolysis caused by the dangerously defective pain pump. He will require

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1 additional surgeries, including shoulder replacements, as a result of the narrowing of the joint space
2 and chondrolysis caused by the dangerously defective pain pump. As a result of his debilitating
3 condition, which is permanent and life-long, Justin currently has and will continue to have difficulty
4 doing the most basic tasks of everyday living. Justin was once a promising junior Olympic
5 swimmer, whose life revolved around his championship swimming abilities. Now his life as he
6 once knew it is over. As his subsequent treating physician, Dr. Brian J. Cole wrote that Justin's
7 "debilitating shoulder pain affects all activities of daily living, and excludes him from any attempts
8 at recreational activities as well." Justin's life is consumed with the devastation of a destroyed
9 shoulder and the prospects of a life of pain and medication. He will suffer lost income, loss of
10 career options, a loss of enjoyment of life, and other damages, all of which were avoidable.

11 18. Justin's parents, Rebecca and Charles Graham, at all times relevant hereto, were
12 previously solely responsible for the health care costs attendant to Justin's injuries, and now share in
13 those costs with Justin.

14 **CAUSES OF ACTION**

15 **COUNT I – NEGLIGENCE**

16 19. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully
17 set forth herein.

18 20. At all times relevant to this action, I-Flow had a duty to exercise reasonable care, and
19 to comply with the existing standards of care, in its preparation, design, research, development,
20 manufacture, inspection, labeling, marketing, promotion and sale of the pain pumps and the
21 anesthetics used in the pumps, which I-Flow introduced into the stream of commerce, including a
22 duty to insure that users would not suffer from unreasonable, dangerous or untoward adverse side
23 effects.
24

21. At all times relevant to this action, I-Flow had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of pain pumps and the anesthetics used in the pumps.

22. At all relevant times, I-Flow knew or reasonably should have known that the pain pumps were unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

- a. Commonly used anesthetics likely to be used in pain pumps, including Marcaine® (bupivacaine), were harmful to human and animal articular cartilage and that toxicity to cartilage increased with the duration of exposure;
- b. Use of pain pumps with continuously injected anesthetics, including Marcaine® (bupivacaine), in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;
- c. Continuous injection of anesthetics, including Marcaine® (bupivacaine), through a catheter, directly into the shoulder joint, for two days or more, had not been adequately tested for safety or effectiveness; and
- d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetics, including Marcaine® (bupivacaine), as designed and instructed outweighed the possible benefits of such use.

23. Based on what I-Flow knew or reasonably should have known as described above, I-Flow deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

- a. In failing to conduct those tests and studies necessary to determine that the use of pain pumps directly into the shoulder joint was dangerous to shoulder cartilage and contraindicated for use;
- b. In failing to instruct or warn the medical community that the safety of pain pumps with continuously injected anesthetics had not been established for use in the shoulder joint space;
- c. In failing to disclose to the medical community that continuous injection of commonly used anesthetics such as Marcaine® (bupivacaine), with or without epinephrine, over two days or more, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

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- d. In failing to include a precaution against placing the catheters of the pain pumps in the shoulder joint space;
- e. In failing to provide to the medical community adequate instructions for the safe use of the devices with continuously injected anesthetics, including Marcaine® (bupivacaine);
- f. In failing to disclose to the medical community that the effectiveness of pain pumps with continuously injected anesthetics, including Marcaine® (bupivacaine), was uncertain for use in the shoulder joint space;
- g. In failing to disclose to the medical community that no tests had ever been done to determine the safety of using the pain pump in the shoulder;
- h. Manufacturing a product to be used with continuously injected anesthetics, including Marcaine® (bupivacaine), designed to directly inject into the shoulder joint commonly used anesthetics associated with damage to articular cartilage;
- i. Manufacturing a product designed to deliver, over time, dangerously high doses of drugs, including Marcaine® (bupivacaine), directly into shoulder tissue; and
- j. Promoting pain pumps and continuously injected anesthetics, including Marcaine® (bupivacaine), for use in the shoulder joint space after the FDA had considered and rejected such an indication.

24. At all relevant times, I-Flow knew or reasonably should have known that the anesthetics used in the pain pumps, including Marcaine® (bupivacaine), were unreasonably dangerous and defective when used as directed and designed, including but not limited to the following particulars:

- a. Commonly used anesthetics likely to be used in pain pumps, including Marcaine® (bupivacaine), were harmful to human and animal articular cartilage;
- b. Use of pain pumps with continuously injected anesthetics, including Marcaine® (bupivacaine), in the shoulder joint space had not been approved by the FDA, and in fact had been specifically rejected by the FDA;
- c. Continuous injection of anesthetics, including Marcaine® (bupivacaine) through a catheter, directly into the shoulder joint, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using pain pumps with continuously injected anesthetics, including Marcaine® (bupivacaine), as designed and instructed outweighed the possible benefits of such use.

25. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Justin and Plaintiffs.

26. The injuries and damages suffered by Justin and Plaintiffs were reasonably foreseeable results of I-Flow's negligence.

27. Had I-Flow performed those tests and studies necessary to determine that pain pumps and the anesthetics used with them, including Marcaine® (bupivacaine), should not be used directly in the shoulder joint before Justin's physician used a pain pump following his surgery, as I-Flow was required to do, he would not have developed chondrolysis and Justin and Plaintiffs would not have suffered the injuries and damages described with particularity, above.

28. I-Flow is directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents, including, but not limited to, its sales representative. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Plaintiffs.

29. As a direct and proximate cause of I-Flow's negligence, Justin suffered the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder and arm, and requiring multiple surgeries. Justin will also require future medical care, including physical therapy, pain management, additional shoulder surgeries as he ages, including but not limited to, shoulder replacements. In addition, Justin has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities, and other damages.

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30. As a direct and proximate cause of I-Flow's negligence, Justin's parents, Rebecca and Charles Graham, have incurred, and may incur in the future, expenses for the medical surgical, therapeutic, rehabilitative, and additional care and other needs and expenses for their son, Justin. Mr. and Mrs. Graham have suffered and will continue to suffer injuries, damages and losses, as alleged herein.

COUNT II – NEGLIGENT MISREPRESENTATION

31. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

32. I-Flow, in the course of their business, negligently misrepresented and communicated to Plaintiffs and/or Justin's physician false information which was relied upon for guidance in their decision to use an ON-Q® PainBuster® pain pump with Marcaine® (bupivacaine) following Justin's shoulder surgery.

33. The false information supplied by I-Flow to Plaintiffs and/or Justin's physician was that the ON-Q® PainBuster® pain pump and the Marcaine® (bupivacaine) used in the pump were safe, effective, and would not harm or adversely affect Justin's health.

34. In making such representations, I-Flow knew or should have known that the representations were false and not completely accurate at the time I-Flow made the representations.

35. The misrepresentations and false information communicated by I-Flow to Plaintiffs and Justin's physician were in fact false and were material and Plaintiffs and Justin's physicians justifiably relied in good faith on Defendants' misrepresentations and false information, all to Plaintiffs' detriment.

36. Those misrepresentations and concealments by I-Flow were made with the intent to advertise, market, and sell pain pumps and anesthetics off-label.

37. As such, I-Flow failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information to Plaintiffs and Justin's physician, and failed to comply with the existing standard of care.

38. I-Flow is directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents, including, but not limited to, its sales representatives. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Plaintiffs.

39. Plaintiffs and Justin's physicians justifiably relied on the misrepresentations and concealments by I-Flow and its agents and sales representatives, and as a direct and proximate result of such reliance, Plaintiffs suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

COUNT III – STRICT PRODUCT LIABILITY

40. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

41. I-Flow placed its pumps into the stream of commerce.

42. Justin is in the class of persons that I-Flow should reasonably foresee as being subject to the harm caused by defectively designed pain pumps, insofar as Justin was the type of person for whom the pumps were intended to be used.

43. I-Flow, which is engaged in the business of selling the products, manufactured and supplied the pain pumps and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

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1 44. The pain pump supplied to Justin was defective in design and formulation and
2 unreasonably dangerous when it left I-Flow's hands, in that the foreseeable risks exceeded the
3 benefits associated with the design and/or formulation.

4 45. The pain pump reached the user and consumer of the product, Justin, without
5 substantial alteration in the condition in which it was sold.

6 46. The pain pump manufactured by I-Flow was unreasonable and dangerously defective
7 beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these
8 products.

9 47. I-Flow's pain pump was defective due to inadequate warning and/or inadequate
10 clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of
11 such studies.

12 48. I-Flow's pain pump was defective due to inadequate post-marketing warning or
13 instruction because, after I-Flow knew or should have known of the risk of injury from their pain
14 pumps, I-Flow failed to provide adequate warnings to the medical community and patients, and
15 continued to promote the products as safe and effective.

16 49. The product defects alleged above were a substantial contributing cause of the
17 injuries suffered by Justin and the Plaintiffs. Specifically, the ON-Q® PainBuster® pain pump
18 caused Justin to suffer the permanent loss of cartilage in his shoulder, resulting in severe pain and
19 discomfort of the shoulder, loss of use and function of the shoulder and arm, and requiring multiple
20 surgeries. The use of the pain pumps and continuously injected anesthetic also rendered the
21 therapeutic benefit of his shoulder surgeries worthless and of no value. Justin will also require
22 future medical care, including additional shoulder surgeries, including but not limited to, shoulder
23 replacement. In addition, Justin has suffered mental distress and anguish and has suffered
24 permanent impairment of the use and function of his affected upper extremities.

50. As a direct and proximate result of the defective condition of I-Flow's products, Justin and his parents suffered and will continue to suffer injuries, damages, and losses, as alleged and described herein.

COUNT IV – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

51. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

52. I-Flow manufactured pain pumps and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

53. I-Flow's pain pumps were defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

54. I-Flow's pain pumps were defective due to inadequate post-marketing warning or instruction because, after I-Flow knew or should have known of the risk of injury from their pain pumps and anesthetics used in the pumps, I-Flow failed to provide adequate warnings to the medical community and patients, and continued to promote the pain pumps as safe and effective.

55. The defective warnings and labeling on the pain pumps were substantial factors in bringing about the injuries to Plaintiffs.

56. As the direct and proximate cause of the defective condition of ON-Q® PainBuster® pain pump, as manufactured and/or supplied by I-Flow, and specifically I-Flow's failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Justin and the Plaintiffs suffered those injuries and damages as described with particularity, above.

COUNT V – FRAUD

57. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

1 58. On May 28, 1998, the FDA approved I-Flow's PainBuster Infusion System for
2 intraoperative use in the soft tissue or body cavity. However, for lack of safety, the FDA denied I-
3 Flow's requests for intra-articular and orthopedic uses:

4 a. On August 20, 1998, I-Flow submitted a 510(k) (K982946) to the FDA
5 seeking to expand the indications for the PainBuster Infusion Kit to include
6 "continuous infusion of a local anesthetic directly into the intraoperative or intra-
7 articular site for postoperative pain management."

8 i. On September 2, 1998, I-Flow issued a press release entitled "I-Flow
9 Corporation (NASDAQ) Signs Letter of Understanding with Smith &
10 Nephew, Inc. to Market I-Flow's 'PainBuster' Infusion Pain Management Kit
11 for Orthopaedic applications," stating that I-Flow received approval in June
12 1998 from the U.S. Food and Drug Administration to market the PainBuster
13 in the United States for orthopaedic surgery applications. This statement was
14 false. In fact, I-Flow never received such approval.

15 ii. The FDA denied I-Flow's application for intra-articular use because I-Flow
16 failed to provide any evidence of safety to satisfy an indication for intra-
17 articular use or for orthopedic surgery.

18 iii. Instead, the FDA approved the PainBuster for the Revised Indications for Use
19 (Nov. 9, 1998), as follows: "The PainBuster is intended to provide
20 continuous infusion of a local anesthetic directly into an intraoperative (soft
21 tissue/ body cavity) site for general surgery for postoperative pain
22 management. Additional routes of administration include percutaneous and
23 subcutaneous infusion."

24 iv. The FDA did not clear the PainBuster to be marketed for intra-articular
administration, nor was it approved for orthopedic surgery as I-Flow
withdrew this orthopedic use indication at the FDA's request.

 b. On November 11, 1998, I-Flow submitted a 510(k) (K984146) to the FDA to
extend the administration set product line for its existing Paragon (intravenous)
infusion system (K923875). On January 13, 1999 I-Flow submitted to the FDA a
revised "Indications for Use" to be used with its Paragon Infusion Kit to include
synovial infusions as an additional indication for use based on another pump
manufacturer, McKinley's, inclusion of synovial cavity infusion as an indication for
use. In response, the FDA denied I-Flow's submission and stated that McKinley
would also be required to modify its Indications for Use Statement to remove
synovial cavity infusions. On February 9, 1999, the FDA cleared I-Flow's Paragon
Infusion Kit for continuous infusion into the intraoperative site and for percutaneous,
subcutaneous, intramuscular and epidural infusion as additional routes of
administration. And, on March 3, 1999, the FDA sent out a correction letter to
McKinley removing the synovial cavity infusion indication for use.

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1 59. Despite FDA's denials of I-Flow's applications for approval to market the PainBuster
2 for orthopedic use and for use in the joint space, on May 12, 1999, I-Flow and DJO entered into a
3 Distribution Agreement which defined the PainBuster as a product that is used for continuous
4 infusion of local anesthetics into the joint space. Thus despite the denials, I-Flow and DJO treated
5 the PainBuster as if it were cleared for orthopedic and intra-articular use.

6 60. Undeterred by the FDA's denials, and in violation of the Code of Federal
7 Regulations, as illustrated in the paragraphs that follow, I-Flow and DJO continued to promote the
8 PainBuster for both intra-articular and orthopedic use until December 2003, at which time I-Flow
9 took over as distributor of its own pumps, and continued to market them, as On-Q PainBusters, for
10 orthopedic use.

11 61. As illustrated in the paragraphs that follow, I-Flow and its agents and sales
12 representatives knowingly, intentionally, directly and/or impliedly made material misrepresentations
13 to Plaintiffs, Plaintiffs' physicians, and to the public that pain pumps and the anesthetics used in the
14 pumps were safe for use following shoulder surgeries, such as Justin Graham's.

15 62. The representations by I-Flow's agents and sales representatives were in fact false, as
16 pain pumps and the anesthetics used in the pumps were not safe for human use following shoulder
17 surgeries, and instead proximately caused narrowing of the joint space, glenohumeral chondrolysis
18 and other injuries and/or adverse side effects.

19 63. When I-Flow's agents and sales representatives made these representations that their
20 pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries
21 such as Justin Graham's, they knew those representations were false, deceptive, and misleading, and
22 they made those false representations with the intent to defraud, deceive, and mislead. For example,
23 on July 21, 1999, Robert Bard, the vice president of regulatory affairs for I-Flow, admitted to Kevin
24 Sumstine of DJO, who had contracted with I-Flow to sell the pain pumps to orthopedic surgeons,

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1 that despite three attempts to secure synovial cavity use in their 510(k), the FDA had rejected this
 2 use each and every time. Thus, I-Flow marketed its pain pumps for orthopedic use in the joint space
 3 knowing it was not approved for those purposes with the intent to defraud, deceive, and mislead
 4 physicians, including Justin Graham's.

5 64. In August 2007, Plaintiff, Plaintiffs' physicians, and the public justifiably relied upon
 6 the misrepresentations of I-Flow's agents and representatives and reasonably believed the
 7 misrepresentations to be true, and in justifiable reliance upon these misrepresentations, were induced
 8 to prescribe and use the On-Q PainBuster and the continuously injected anesthetics.

9 65. I-Flow utilized multiple marketing tools and methods to promote this off-label use
 10 that had been specifically rejected by the FDA. In fact, I-Flow engaged in full spectrum marketing
 11 of their pain pumps to orthopedic surgeons, including comprehensive marketing (dinner meetings, I-
 12 Flow appreciation night with ball games, cruises, etc., physician reimbursement lunches); value
 13 added programs (pens, post-it notes, and other giveaways); resource utilization (inside sales);
 14 education (in-service materials, catheter placements); incentive programs (patient challenges,
 15 support team appreciation gifts); and partnership marketing with distributors and drug companies.
 16 All of these marketing techniques are described in I-Flow's "One-to-One Marketing Tactics"
 17 authored by Vice President of Marketing, Orlando Rodrigues, on February 5, 2004.

18 66. Through its marketing techniques, I-Flow made representations that its pain pumps
 19 and the anesthetics used in the pumps were safe for use following shoulder surgeries such as Justin
 20 Graham's. For example,

21 a. I-Flow sales representative, Cheryl Pritchard, testified on February 20, 2009,
 22 that I-Flow trained sales staff specifically to promote orthopedic, intra-articular use;

23 b. I-Flow equipped sales staff with direction sheets for techniques regarding
 24 placement of the pump within the joint and used medical liaisons to give favorable
 presentations at conferences. For example, on October 16, 2006, I-Flow Group
 Marketing Director, Julie Schneider provided to a Territory Manager a PowerPoint
 presentation to show to an orthopedic surgeon that might serve as one of I-Flow's

speakers. Two of the slides in that presentation discuss glenohumeral joint placement.

c. In fact, I-Flow prepared PowerPoint presentations for physicians to use, which included slides expressly stating that the pumps were particularly useful in shoulder and other joint surgery. One such PowerPoint was sent from I-Flow Field Sales to doctors and customers on or about May 10, 2001. Another such PowerPoint was developed by I-Flow marketing employee, Kathy Thompson, on or about November 26, 2001, and described orthopedic shoulder procedures indicating catheter placement in the joint.

d. I-Flow's marketing went so far as to instruct physicians on catheter placement. For example, I-Flow developed ON-Q Catheter Placement Technique guides which specified that the pain pump catheters could be placed intra-articular (in the joint space). One such guide was developed by I-Flow on or about July 10, 2002 for a presentation by a surgeon at Green Hospital/Scripps clinic in San Diego.

e. In addition, I-Flow created marketing brochures that were available in the orthopedic surgeons' offices across the country, including Nevada, explaining to the patient that a pain pump had been placed in the joint to provide pain relief following surgery; and, that there was nothing that the patient needed to do; the pump worked by itself. For example, one such document was created by I-Flow on or about October 21, 2005 for use by an orthopedic physician in Brighton, Michigan.

67. When I-Flow and its agents and sales representatives made these representations that its pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries such as Justin Graham's, it knew those representations were false, deceptive, and misleading, and they made those false representations with the intent to defraud, deceive, and mislead.

68. Roger Massengale, Director of Marketing and Business Development for I-Flow, testified on July 1, 2008 that I-Flow never studied, nor commissioned a study to determine the safety of its infusion pain pumps using commonly used anesthetics in the shoulder. Yet, I-Flow continued to market these products for that use.

69. Alan Dine confirmed in his deposition on December 16, 2008 that an efficacious and safe dosage for intra-articular administration had never been determined in any clinical study designed by I-Flow for this purpose. Yet, I-Flow continued to market its pain pumps for that use.

70. I-Flow had actual notice that patients were suffering devastating injuries to their joints when I-Flow pain pumps were used in orthopedic surgeries.

a. For example, I-Flow first received reports of chondrolysis on July 27, 2004, when I-Flow Territory Manager, Cheryle Pritchard, reported to Alan Dine, I-Flow's Director of Clinical Research that eight college age patients had developed chondrolysis following use of a pain pump. Mr. Dine testified on December 16, 2008 that he did not to investigate these reports; indeed, he did not to follow up with Ms. Pritchard regarding these complaints, and he did not to attempt to contact the physician, Dr. James Andrews, whose patients were the subject of Ms. Pritchard's report to Mr. Dine. Ms. Pritchard's report occurred two months after an FDA officer wrote an article in the journal, *Anesthesiology*, discussing adverse events reported to the FDA that were associated with the use of pain pump systems. Yet, in violation of FDA regulations, I-Flow did nothing to investigate the circumstances surrounding this report.

b. In January 2006, an orthopedic surgeon in Montana notified I-Flow of three patients, female athletes with no history of health problems, who developed chondrolysis following the use of an I-Flow pump. That report also advised of 15 other cases of chondrolysis by another physician in Salt Lake City who attributed the cause to the pain pump, and that other surgeons had expressed concern about this same issue.

c. On March 23, 2006, I-Flow's representatives attended a presentation by Dr. Beck at the annual meeting of the American Academy of Orthopedic Surgeons. At this presentation, Drs. Hansen and Beck presented compelling medical evidence that associated chondrolysis with the continuous infusion of local anesthetic from a pain pump like the one manufactured and distributed by I-Flow. I-Flow's officers and directors, including Alan Dine, Roger Massengale, I-Flow's Vice President of Marketing and Business Development, and Barbara Saint John, I-Flow's Director of Sales Training, had actual knowledge of Drs. Hansen and Beck's presentation and their research results. Following the presentation, the aforementioned officers and directors, among others, chose not to perform additional research, did not issue a warning to physicians, and chose not to send a Dear Doctor letter.

71. The March 23, 2006 presentation by Hansen and Beck prompted multiple inquiries about chondrolysis and its relationship to the use of infusion pumps. I-Flow's response to the growing number of inquiries was not concern for the safety of its customers, rather, a March 31, 2006 email exchange between Alan Dine and Barbara Saint John, Director of Sales Training and Clinical Education, shows that I-Flow's concern was to squelch the fire before it could do too much damage to I-Flow.

1 72. On June 27, 2006, Cheryle Pritchard again reported to I-Flow a number of
2 chondrolysis cases from multiple surgeons, including one who had advised Ms. Pritchard that she
3 should discourage surgeons from using the pain pump in the joint. In this same report, Ms.
4 Pritchard stated that many, many surgeons bring this topic up to her every day.

5 73. In September 2006, a financial analyst for I-Flow brought to I-Flow's attention yet
6 another incidence of chondrolysis and that the surgeon had come to the conclusion that the
7 continuous infusion of local anesthetic into the joint was responsible for the damage.

8 74. Undaunted, as illustrated in paragraph 51(b) above, I-Flow continued to provide
9 physicians with information about placing the pain pump catheter into the joint space.

10 75. Roger Massengale testified on December 9, 2008 that following the Hansen and
11 Beck presentation in March 2006 and after receiving complaints in 2006 and 2007, I-Flow engaged
12 in no efforts to promote a study to determine the nature of this crisis and even turned away a
13 researcher who was seeking support for such a study.

14 76. While I-Flow was receiving these reports of chondrolysis, I-Flow was contacted by a
15 researcher from Stanford Medical School, Dr. Jason Dragoo, who requested 8 I-Flow pain pumps
16 for use in an in vitro study. On July 24, 2006, Barbara Saint John responded that she would provide
17 the pumps; however, one month later, when I-Flow realized that Dr. Dragoo wanted to study
18 chondrolysis and not efficacy, I-Flow withdrew its support.

19 77. I-Flow changed its package insert in the fall of 2006 to include a warning to avoid
20 placing the catheter into the joint; however, Roger Massengale testified that I-Flow knew at that
21 time that the new product insert would not accompany the product until the next year. Despite this
22 knowledge, Diana Kramer, Senior Product Director, testified on December 18, 2008 that I-Flow did
23 not recall any pain pumps that contained the old package inserts. In addition, Barbara Saint John
24

1 testified that I-Flow did not advise any physicians about the need to read the label for new safety
2 information, or that the label had been changed.

3 78. I-Flow had the capacity to use vendors to reach out to all orthopedic surgeons
4 nationally with a technical bulletin which provides information to healthcare providers regarding I-
5 Flow's products. In the fall of 2006, I-Flow prepared a Technical Bulletin entitled, "Continuous
6 Infusion in Restrictive Spaces: Volume and Flow Rate Selection," to include a warning. On
7 October 20, 2006, the day that the Technical Bulletin was supposed to be communicated to I-Flow's
8 customers, the CEO of I-Flow, Donald Earhart, cancelled the distribution of the technical bulletin
9 and requested that it be immediately removed from the website.

10 79. In September 2007, I-Flow finally issued a technical bulletin entitled "What we know
11 about Chondrolysis Today." However, this inadequate gesture was three years after Cheryl
12 Pritchard reported the Andrews cluster; over 1.5 years after learning of the Montana/Hansen
13 clusters; one year after drafting a warning on its Directions for Use; and one month after Justin
14 Graham's orthopedic surgeon inserted the I-Flow pain pump catheter into Justin's shoulder joint so
15 that it would be continuously infused with local anesthetic following his surgery.

16 80. I-Flow is directly liable for the negligent and/or fraudulent conduct of its actual
17 and/or ostensible employees, servants, and agents, which includes, but is not limited to, its sales
18 representatives. The negligent and/or fraudulent conduct of these employees, servants, and actual
19 and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the
20 grievous injuries and damages sustained by Plaintiffs.

21 81. As a result of the fraud of I-Flow's agents and sales representatives, Plaintiffs
22 suffered and will continue to suffer injuries, damages, and losses as alleged herein.

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COUNT VI – PUNITIVE DAMAGES

82. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

83. I-Flow's acts, conduct, and omissions, as alleged throughout this Complaint, were willful, malicious, and oppressive as those terms are defined in NRS 42.001, and were done with a conscious disregard for the rights and safety of Justin and other users of I-Flow's products, warranting the imposition of punitive damages against I-Flow, pursuant to NRS 42.005(1) and 2(a), in an amount appropriate to punish and deter such conduct in the future.

WHEREFORE, Plaintiffs demand judgment against I-Flow as follows:

- a. Compensatory damages in an amount in excess of \$75,000.00 as provided by law and to be supported by the evidence at trial;
- b. Punitive or exemplary damages in an amount sufficient to punish I-Flow and deter such conduct in the future;
- c. An award of attorneys' fees, pre-judgment and post-judgment interest, and the costs of suit, as provided by law; and
- d. Such other legal and equitable relief as this Court deems just and proper.

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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: June 17, 2010

Respectfully submitted,

By: /s/ Peter C. Wetherall
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CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2010, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to all registered CM/ECF registrants for this case.

By /s/ Peter C. Wetherall
An employee of White & Wetherall, LLP

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